

### **REMARKS**

The present Office Action addresses and rejects claims 1-30. Applicant respectfully requests reconsideration in view of the amendments and remarks herein.

#### ***Objection to the Drawings***

Applicant has amended the specification to correct a typographical error in Paragraph [0016] and to include reference characters for all numbered elements in the drawings. Some reference character subscripts were inadvertently deleted when the application was electronically submitted to the Patent Office. The amendments add no new matter to the disclosure.

#### ***Amendment to the Claims***

Claim 1 is amended to recite that opposed first and second helical threads of the bone screw extend around at least a portion of *the proximal and distal portions* of the shank. Support for this amendment can be found throughout the specification, for example in paragraph [0014] and in FIGS. 1-3 and.

Claim 30 is amended to recite that the threads are formed on at least *the distal portion* of the shank. Support for this amendment can be found throughout the specification, for example in paragraph [0017].

No new matter is added.

#### ***Rejections Pursuant to 35 U.S.C. § 103***

##### **Shadduck and Ballintyn**

Claims 1-2, 6-8, 10-12, 14-17, 21-22, and 25-30 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,503,251 ("Shadduck") in view of U.S. Patent No. 5,584,836 ("Ballintyn"). Applicant respectfully disagrees.

*Claims 1-2, 6-8, 10-12, 14-15*

Independent claim 1 as amended recites a bone screw that includes a head and a shank having a proximal portion with a constant minor diameter, and a distal portion with a minor diameter that decreases in a proximal-to-distal direction. Claim 1 also recites opposed first and second helical threads extending around at least a portion of the proximal and distal portions of the shank and defining a thread depth that remains constant along the length of the shank.

Shadduck does not teach or suggest “a shank having a proximal portion with a constant minor diameter, and a distal portion with a minor diameter that decreases in a proximal-to-distal direction; and opposed first and second helical threads, the threads extending around at least a portion of the proximal and distal portions of the shank” as required by Applicant’s claim 1. Shadduck discloses a screw body (20) having a constant diameter between the proximal and distal ends (21, 22). While the screw does include a tapered nose portion (33) that decreases in diameter, the helical thread (29) does not extend around the tapered nose portion (33). As most clearly illustrated in Shadduck FIGS. 1-2 and 6-7, the screw body (20) therefore does not have a proximal portion with a constant minor diameter and a distal portion with a minor diameter decreasing in a proximal-to-distal direction with a helical thread extending around at least a portion of the proximal *and distal* portions as required by claim 1.

Ballintyn does not remedy the deficiencies of Shadduck. As best shown in FIGS. 1B, 2B, and 3B, the screw of Ballintyn maintains a constant diameter along its body and thus does not have “a distal portion with a minor diameter that decreases in a proximal-to-distal direction” as required by claim 1.

Accordingly, independent claim 1, as well as claims 2, 6-8, 10-12, and 14-15 which depend therefrom, therefore distinguish over Shadduck and Ballintyn and represent allowable subject matter.

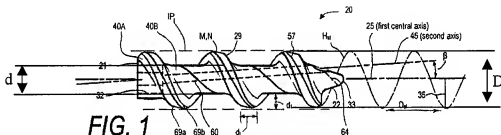
*Claims 16-17, 21-22, and 25-29*

Independent claim 16 recites a bone screw that includes a head having a driver-receiving

element formed thereon. Claim 16 also recites a shank formed from first and second axially symmetrical threads offset approximately  $180^\circ$  from one another and extending around at least a portion of the shank between proximal and distal ends. The threads have a depth that remains constant along a length of the shank, and a proximal portion of the shank has a minor diameter that is equal to or greater than a major diameter of the shank at a distal-most end.

First, Shadduck fails to teach or even suggest “first and second axially symmetrical threads offset approximately  $180^\circ$  from one another,” as required by independent claim 16. Shadduck discloses a bone screw formed from two helical members 40A, 40B that mate to form a single helical thread. When inserted into bone, one of the members is moved relative to the other member to cause the threads to extend at an angle relative to one another. In particular, the axes of the threads are angularly offset from one another by about  $1^\circ$  to  $20^\circ$ . (See Col. 5, lines 14-24.) The threads are not positioned  $180^\circ$  apart from one another, as required by claim 16.

Second, Shadduck further fails to teach or even suggest “a proximal portion of the shank having a minor diameter that is equal to or greater than a major diameter of the shank at a distal-most end thereof.” As shown in FIG. 1 of Shadduck, which is reproduced below with markings, the minor diameter (d) of the shank at the proximal portion is not equal to or greater than the major diameter (D) of the shank at the distal-most end thereof. To the contrary, the minor diameter (d) at the proximal portion is significantly *less* than the major diameter (D) at the distal-most end of the screw.



Shadduck is therefore deficient as a reference for several reasons. Ballintyn does not remedy the deficiencies of Shadduck. Ballintyn only discloses one screw thread (2) and thus

does not have “first and second axially symmetrical threads offset approximately 180° from one another,” as required by claim 16. Ballintyn also fails to teach the claimed diameters, as the minor diameter of the shank along the entire length of the shank is less than – not equal to or greater than – the major diameter of the shank.

Accordingly, independent claim 16, as well as claims 17, 21-22, and 25-29 which depend therefrom, therefore distinguish over Shadduck and Ballintyn and represent allowable subject matter.

*Claim 30*

Independent claim 30 recites a bone screw that includes a head and a shank having a proximal portion with a constant minor diameter, and a distal portion with a minor diameter that decreases in a proximal-to-distal direction. Opposed first and second helical threads are formed on at least the distal portion of the shank and they define a major diameter that decreases at the same rate as the minor diameter of the shank.

Shadduck does not teach or even suggest a bone screw having a shank with a distal portion having a minor diameter that decreases, and threads formed on at least the distal portion with a major diameter that decreases at the same rate as the minor diameter of the shank. As shown in FIG. 1 above, Shadduck’s bone screw has threads with a constant major diameter. The major diameter of the threads does not decrease. In fact, the only portion of the bone screw with a diameter that decreases is the distal-most tip of the bone screw. The threads, however, do not extend over the distal-most tip. Thus, claim 30 distinguishes over Shadduck’s.

Ballintyn does not remedy the deficiencies of Shadduck, as Ballintyn likewise fails to teach threads having a major diameter that decreases. Like Shadduck, Ballintyn’s screw has threads with a constant major diameter.

Accordingly, independent claim 30 distinguishes over Shadduck and Ballintyn and represents allowable subject matter.

Shadduck, Ballintyn, and Schlapfer


Dependent claims 3-5, 9, 13, 18-20, and 23-24 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Shadduck in view of Ballintyn and in further view of Schlapfer. Applicant respectfully disagrees. At least for the reasons explained above, independent claims 1, 16, and 30 distinguish over Shadduck and Ballintyn. Schlapfer fails to cure the deficiencies of Shadduck and Ballintyn, as Schlapfer is merely relied on to disclose distinct features recited in the dependent claims. Accordingly, claims 3-5, 9, 13, 18-20, and 23-24 are allowable at least because they depend from an allowable base claim.

**Conclusion**

Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant's amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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